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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,773	04/14/2005	Allen D. Delaney	SMAR-044	3141

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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,773	DELANEY, ALLEN D.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,12,15-17,28 and 43* is/are pending in the application.

4a) Of the above claim(s) *2,7,12,15-17,28 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Election filed 2/7/07 in response to the Office Action of 8/8/06 is acknowledged and has been entered. Applicant elected group 1 and a polypeptide encoded by SEQ ID NO:1 and a polypeptide having the amino acid sequence of SEQ ID NO:2 with traverse.

The traversal is on the ground(s) that the examination of all groups would not impose a serious burden on the examiner. Applicants further point to MPEP 803. These arguments have been considered but are not found persuasive as such arguments do not apply when restriction is required under 35 USC 121 and 372, as in the instantly filed application. Thus, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said

product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. The allowed combinations do not include multiple products (antibodies, nucleic acids, polypeptides), and multiple methods of using said products, as claimed in the instant application. The products themselves do not share significant structural elements to the extent that each member could be substituted, one for the other, with the expectation that the same intended results would be achieved. For example, the polynucleotide sequences comprise significant differences in chemical compositions and lengths which, in turn, encode a multitude of amino acids with different chemical compositions and lengths all of which would have different molecular weights, specificities, and biological activities. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application is considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group 1 is the main invention. After that, all other products and methods are broken out as separate groups (see 37 CFR 1.475(d).).

In the instant case, the first invention of the first category mentioned consists of a method of screening for biologically active agents comprising combining a candidate biologically active agent with a specific polypeptide and determining the effect of said agent on phosphatase function. It is noted that there is no recited "process of manufacture" of the specific polypeptides of group I and product claims are not drawn to

the polypeptides recited in the method of group I. Therefore, a method of screening for biologically active agents comprising combining a candidate biologically active agent with a specific polypeptide and determining the effect of said agent on phosphatase function is considered the "main invention" and the remaining products and methods have been properly restricted into separate groups.

Further, it is noted that the application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The technical feature linking groups I-XII appears to be that they all relate to the special technical feature of a method of screening for biologically active agents that modulate a cancer associated phosphatase function, the method comprising, combining a candidate biologically active agent with a polypeptide encoded by SEQ ID NO:1 or having the amino acid sequence as set forth in SEQ ID NO:2 and determining the effect of said agent on phosphatase function. However, Plowman et al (WO 01/12819 A2; 2/22/01) teaches a method of screening for biologically active agents that modulate a cancer associated phosphatase function, the method comprising, combining a candidate biologically active agent with a polypeptide encoded by SEQ ID NO:1 or having the amino acid sequence as set forth in SEQ ID NO:2 and determining the effect of said agent on phosphatase function (see page 27 and SEQ ID NO:12, in particular). Therefore, the technical feature linking the inventions of groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive

concept. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1, 2, 7, 12, 15-17, 28, and 43 are pending.

Claims 2, 7, 12, 15-17, 28, and 43 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claim 1 is currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of polypeptides encoded by SEQ ID NO:1. It is noted that the genus of polypeptides encoded by SEQ ID NO:1 broadly reads of any polypeptide encoded by a fragment of SEQ ID NO:1. However, the written description in this case only sets forth the polypeptide set-forth as SEQ ID NO:2 as a polypeptide encoded by SEQ ID NO:1. The specification does not disclose any other polypeptides encoded by SEQ ID NO:1 as broadly encompassed in the claims.

The state of the art is such that Plowman et al (WO 01/12819 A2; 2/22/01) teaches the polypeptide set-forth as SEQ ID NO:2 as a polypeptide encoded by SEQ ID NO:1; however, the teachings of Plowman et al are not representative of the broad genus of polypeptides encoded by SEQ ID NO:1.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of sequences that encompass the genus nor does it provide a description of structural features that are common to the genus. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of SEQ ID NO:2 is insufficient to describe the

genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Plowman et al (WO 01/12819 A2; 2/22/01).

Plowman et al teaches the polypeptide set-forth as SEQ ID NO:12, which is 100% homologous to instant SEQ ID NO:2 and is encoded by a fragment 100% homologous to instant SEQ ID NO:1 (see attached sequence comparisons). Plowman et al further teaches a method of screening for biologically active agents that modulate a cancer associated phosphatase function, the method comprising, combining a candidate biologically active agent with the polypeptide set-forth as SEQ ID NO:12 and determining the effect of said agent on phosphatase function (see pages 6, 8, and 27, in particular)

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

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